GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:1443
ANSWERED ON:03.05.2016
Production Cost of Medicines
Dwivedi Shri Harish

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the production cost of non-controlled drugs is many times higher than that of price controlled drugs, if so, the details thereof;

(b) the steps taken by the Government in this regard;

(c) whether the Government has formulated any policy to lower the prices of drugs for cancer and AIDS as well as of other life-saving drugs, if so, the details thereof;

(d) whether some pharmaceutical companies have threatened to stop manufacturing of drugs in protest against this policy; and

(e) if so, the reaction of the Government thereto?

Answer

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS& FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a) to (b): There is no specific provision in the DPCO, 2013 to examine and regulate the actual cost of production of medicines with reference to the ceiling prices / retail prices, as DPCO 2013 follows a market based methodology instead of cost-based methodology.

(c) to (e): Pursuant to the announcement of National Pharmaceutical Pricing Policy, 2012, (NPPP, 2012) Government notified Drugs (Prices Control) Order, 2013 (DPCO, 2013) on 15th May, 2013. All medicines specified in the National List of Essential Medicines 2011 (NLEM) have been included in the First Schedule of DPCO, 2013. NPPA fixed the prices of 530 medicines under First Schedule of DPCO, 2013 (including 53 medicines for cardiovascular disease, 6 anti-diabetics, 20 anti-HIV/AIDS, 24 anti-Tuberculosis (TB), 47 anti-Cancer and 6 medicines for Kidney disease) based on market based pricing methodology as enunciated in NPPP, 2012.

NLEM 2015 has been notified vide Ministry of Health and Family Welfare notification dated 27th December, 2015. Department of Pharmaceuticals vide notification dated 10.03.2016 has amended Schedule-I of DPCO, 2013 substituting NLEM, 2011 with NLEM, 2015. Ceiling Price of 226 scheduled medicines of revised Schedule I (including 20 medicines for cardiovascular disease, 5 anti-diabetics, 14 anti-HIV, 12 anti-tuberculosis (TB) and 29 anti-cancer) have also been fixed.

NPPA has also fixed the retail price of 289 'new drugs' which fall within the purview of Para 2(u) of DPCO, 2013 under Para 5 of DPCO, 2013.

In addition, maximum retail price (MRP) was capped under Para 19 of DPCO, 2013, in respect of 106 non scheduled medicines vide price notification date 10.07.2014, out of which 84 are used for treatment of cardiovascular diseases and 22 for diabetes. The price notifications have been challenged in the Delhi High Court and Bombay High Court where the matter is sub-judice. The Government is defending the price notifications in both the Courts. A large number of manufacturers have already implemented the price reduction and the price notifications of 10.07.2014 issued by the NPPA are still in operation.

****